

# STATE OF TENNESSEE BUREAU OF TennCare DEPARTMENT OF FINANCE AND ADMINISTRATION 310 GREAT CIRCLE ROAD NASHVILLE, TENNESSEE 37228

#### The State of Tennessee, TennCare Bureau

## Pharmacy PARTICIPATION AGREEMENT For Ambulatory and Long Term Care Pharmacy Providers

THIS AGREEMENT ef	ffective July 1, 200	6 is between th	ie State of T	Tennessee,	TennCare	Bureau,	
Department of Finance	e and Administration	n (hereinafter re	eferred to as	TennCare)	and		
(hereafter referred to as Pharmacy).							

WHEREAS, the State of Tennessee, TennCare Bureau is responsible for the financial, clinical and managerial aspects of the TennCare pharmacy program for TennCare/Medicare enrollees and behavioral health pharmacy services and the total pharmacy benefit for all TennCare enrollees after July 1, 2003; and

WHEREAS, the Pharmacy is desirous to participate in contractual prescription filling activities under this TennCare program; and

WHEREAS, the State of Tennessee, TennCare Bureau provides drug benefit programs to TennCare enrollees through arrangements with regional and statewide pharmacy networks; and

WHEREAS, participating pharmacies are members of the TennCare Bureau's network, contractually bound to meet TennCare standards, including but not limited to, emergency services, maintenance and review of patient profiles, patient consultation and medication information and utilization review; and,

WHEREAS, the Pharmacy and TennCare desire to promote high standards of pharmaceutical care on a cost effective basis through drug utilization review activities.

#### SECTION 1 DEFINITIONS

**Section 1.1: Definitions.** The following terms shall have the following meaning:

**Ambulatory Pharmacy:** A chain drug store or independent pharmacy or any other entity licensed by the Tennessee Board of Pharmacy, or an entity duly licensed by any State Pharmacy Board, to dispense prescriptions to outpatient clients in any ambulatory setting.

**Average Wholesale Price:** The average wholesale price (A.W.P.) for a pharmaceutical product as established in the First Data Bank price file and updated no less than twice monthly.

**Co-payment Charge or Co-insurance Charge:** The amount certain TennCare enrollees are required to pay for certain Pharmaceutical Services in accordance with the TennCare waiver.

**Customary Charge:** The reasonable, usual and customary fees charged by Pharmacy which do not exceed the fees Pharmacy would charge any other person regardless of whether the person is a TennCare enrollee.

**Deductible:** The annual amount of charges for Pharmaceutical Services and/or medical expenses as provided in the TennCare waiver that the TennCare enrollee is asked to pay.

**Preferred Drug List (PDL):** TennCare uses a PDL, listing therapeutic categories reviewed by the TennCare Pharmacy Advisory Committee (TPAC). The PDL will be updated quarterly, at a minimum. Changes to the PDL will be communicated to prescribers and pharmacists via electronic mail, U.S. mail, professional societies and website postings. The current TennCare PDL can be found at the website <a href="https://tennessee.fhsc.com">https://tennessee.fhsc.com</a>. Coverage and reimbursement for legend and OTC drugs by the TennCare program is contingent upon a prescription written by a licensed prescriber. OTC drugs that are required to be floor stock items in a long term care facility will not be covered for nursing home residents.

**Long Term Care Facility:** A long-term care facility (nursing home) is a facility planned, staffed, and equipped to accommodate individuals who do not require the degree of care or treatment normally given by a hospital, but who are in need of a wide range of medical, nursing, pharmacy and related health and social services which are provided by appropriately licensed healthcare professionals. TennCare defines a Long Term Care pharmacy recipient as one having a valid PAE (pre-admission evaluation) provider code found in the recipient's eligibility record. Included ranges are 7440000-7440999 and 0445000-0445899. Excluded codes are 7440700 (PACE program) and 04459XX (HCBS program).

**Long Term Care Pharmacy Provider:** Any entity licensed by the Tennessee Board of Pharmacy or duly licensed by any State Pharmacy board to dispense prescriptions to or for residents of long term care facilities (nursing homes).

**Maximum Allowable Cost Limit (MAC):** The list of pharmaceutical products that will be reimbursed at a generic product level established by TennCare. The MAC list includes, adjacent to each pharmaceutical product listed, the corresponding maximum allowable cost per unit that will be used in calculating the reimbursement by TennCare to Pharmacy. This list is subject to periodic review and modification by TennCare.

Network: The group of pharmacies participating in this TennCare program and subject to this agreement

Participating Pharmacy Provider Number: Each Pharmacy which signs this agreement and all other necessary participating pharmacy provider application forms will always use their assigned NCPDP (formerly known as NABP) number when submitting pharmacy claims to TennCare. This number must accompany all claims for reimbursement and all correspondence or communication with the TennCare Bureau.

**Pharmaceutical Product:** A medication or a pharmaceutical product or device which has been prescribed for an eligible TennCare enrollee by an authorized prescriber.

**Pharmaceutical Service:** A pharmaceutical product or service provided to TennCare enrollees for outpatient administration or for administration in a long term care facility which is covered under this TennCare program and meets the criteria set forth in TennCare Pharmacy Manual.

**Prescriber:** A Doctor of Medicine or other health care professional who is duly licensed and qualified under the laws and jurisdiction of Tennessee in which Pharmaceutical Services are received and may in the usual course of his or her practice legally prescribe pharmaceutical products for TennCare enrollees.

**Prescription Order or Refill:** The authorization for the dispensing of a pharmaceutical product issued by a Prescriber who is duly licensed to make such authorization in the ordinary course of his or her professional practice.

**TennCare enrollees:** An individual who is properly enrolled for coverage under TennCare, including beneficiaries of the Medicare Program benefits administered by the Centers for Medicare and Medicaid Services ("CMS") division of the United States Department of Health and Human Services (also known as a TennCare enrollee or TennCare member).

#### SECTION 2 PROVISION OF PHARMACEUTICAL SERVICES

Section 2.1: Provision of Pharmaceutical Services and Quality of Services. Pharmacy shall provide Pharmaceutical Services to all TennCare enrollees in accordance with the standard of practice of the communities in which Pharmacy provides Pharmaceutical Services and in a manner so as to assure the quality of those services. TennCare will monitor the quality of services delivered under the Agreement and initiate corrective action where necessary to improve quality of care. Pharmacy shall provide Pharmaceutical Services without regard to race, religion, sex, color, national origin, age, or physical or mental health status. Pharmacy may not refuse to provide medically necessary or covered preventive services to a TennCare patient based upon non-medical reasons.

Section 2.2: Compliance with the TennCare PDL and TennCare Pharmacy Manual. In providing any pharmaceutical service to a TennCare enrollee, Pharmacy shall comply with the TennCare PDL. Pharmacy will assist the TennCare Bureau in gaining PDL compliance from prescribers. Pharmacy agrees further that it shall at all times comply with the TennCare Pharmacy Manual in providing Pharmaceutical Services to TennCare enrollees.

**Section 2.3: Compliance With Policy On Drug Distribution:** In providing pharmaceutical services to a covered enrollee in a long term care facility (nursing home), pharmacy agrees to comply with TennCare program standards which include a delivery system which allows the pharmacy to credit TennCare for unused, creditable doses on a monthly basis.

Section 2.4: Collection of Co-Payments, Co-Insurance, Deductibles, and Ancillary Charges. Pharmacy shall collect any Co-payments, Co-Insurance Charges, Deductibles, Ancillary Charges, or other charges for Pharmaceutical Services provided by Pharmacy to TennCare members, as may be specified or required in the TennCare Pharmacy Manual and as required by TennCare. However, Pharmacy <a href="may not refuse to provide">may not refuse to provide</a> pharmacy services to TennCare members solely because the member is unable to pay a pharmacy co-payment, as required by federal law. If the recipient has another primary insurance and the pharmacy is aware of other insurance, then the pharmacy must process the transaction in such a manner that TennCare is the "payer of last resort".

**Section 2.5: Utilization Management and Quality Assurance.** Pharmacy shall cooperate with all utilization review management, quality assurance, peer review, and other similar programs established by TennCare, including those performed by Pharmacies working for TennCare.

**Section 2.6: Payment for Zero Balance Claims.** TennCare requires that Pharmacy submit all claims for Pharmaceutical Services, even zero balance claims. This information is necessary for TennCare's Drug Utilization Review (DUR) activities and will be audited by TennCare periodically.

Section 2.7: Submission of Claims. Upon TennCare's request and as set forth in the TennCare Pharmacy Manual, Pharmacy shall submit all claims for Pharmaceutical Services provided under this Agreement via the TennCare POS on-line pharmacy claims processing system to TennCare for adjudication of such claims. All ambulatory pharmacy claims must be submitted via the online point-of-sale (POS) pharmacy claims processing system vendor contracted with the TennCare Bureau. Long term care pharmacy claims for eligible, TennCare/Medicare enrollees must be submitted via online or batch electronic claims media to the vendor contracted with the TennCare Bureau. Pharmacy claims may be submitted to TennCare up to three hundred sixty-five (365) days from the original date of service, unless otherwise approved by TennCare.

**Section 2.8: Non-Exclusivity.** This Agreement shall not prohibit any participating pharmacy from participating with any other third party payors.

**Section 2.9: Prior Authorization and Emergency supply.** In circumstances in which prior authorization is required, the pharmacist must attempt to contact the prescriber to advise him/her that the patient will be unable to fill the full prescription unless: 1) the prescriber changes the prescription to a drug that does not require PA, or 2) seeks and obtains a prior authorization for the original prescription. If the pharmacist is able to reach the prescriber and resolve the matter, the pharmacist is not required to provide the enrollee with the "Prior Authorization Required" form. In that circumstance, the pharmacist will either:

- 1. Dispense a drug to the enrollee (because the prescriber obtained a PA or made a therapy change to a drug for which no PA was required), or
- 2. Inform the enrollee that the prescriber has withdrawn the original medication order

If the pharmacist is unsuccessful in reaching the prescriber and/or resolving the matter, the pharmacist must provide the enrollee with the "Prior Authorization Required" form. If the pharmacist does reach the prescriber and he/she indicates that he/she will seek PA (but it hasn't been obtained yet), the pharmacist must still give the enrollee the "Prior Authorization Required" form, but may advise the enrollee that a PA request is pending.

An emergency supply is one that is dispensed in an emergency situation. An emergency situation is a situation that, in the judgment of the dispensing pharmacist, involves an immediate threat of severe adverse consequences to the enrollee, or the continuation of immediate and severe adverse consequences to the enrollee, if an outpatient drug is not dispensed when a prescription is submitted. Pharmacists will have the discretion to dispense an emergency supply (72 hours, 3 days) in the event that medication prescribed requires a prior authorization. Within those three (3) days the prescriber must either make a therapy change to a drug that does not require prior authorization or contact the Pharmacy Benefit Manager (PBM) to obtain a prior authorization. If the prescriber does not obtain PA, TennCare will not cover the remainder of the prescription for the enrollee.

There are certain exceptions in which a 3-day emergency supply would not be dispensed:

- a) Adult TennCare recipients (>21 years old)
  - a. Medications used for anorexia or weight loss (Meridia<sup>®</sup>, Xenical<sup>®</sup>, etc.)
  - b. Medications used to promote fertility (Clomid<sup>®</sup>, Chorionic Gonadotropin, etc.)
  - c. Medications used for cosmetic purposes or hair growth (Rogaine<sup>®</sup>, etc.)
  - d. Medications used for the symptomatic relief of cough and colds (combination decongestant/antihistamine, etc.)
  - e. Medications used to promote smoking cessation (Zyban<sup>®</sup>, Nicorette<sup>®</sup>, etc.)
  - f. Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations. (Berocca Plus<sup>®</sup>, etc.)
  - g. Non-prescription medications (not covered on the approved OTC list)
  - h. Barbiturates
  - i. Benzodiazepines
  - Prescriptions over the monthly limit (for recipients subject to benefit limits).
- b) All TennCare recipients:
  - a. Medications classified as DESI (Drug Efficacy Study and Implementation), LTE (Less than effective), or IRS (Identically related or similar)

**Section 2.10: Credentialing/Reimbursement.** Pharmacy shall be obligated to participate in any and all TennCare pharmacy credentialing programs. Failure to participate in or successfully complete this program may result in termination of this agreement.

**Section 2.11: Professional or Technical Expertise.** Pharmacy shall be licensed in the jurisdictions in which it practices and shall employ only licensed pharmacists and shall satisfy the credentialing requirements of TennCare. Further, by agreeing to be bound by the Participation Agreement, Pharmacy assures that the functions and/or services it provides are within the scope of its pharmacists' professional/technical practice.

**Section 2.12: Adherence to TennCare Standards.** Pharmacy shall adhere to the TennCare Quality Standards as developed by TennCare.

## SECTION 3 PAYMENT FOR PHARMACEUTICAL SERVICES

Section 3.1: Payment for Pharmaceutical Services. TennCare shall pay Pharmacy in accordance with the TennCare Pharmacy Manual for Pharmaceutical Services provided by Pharmacy to a TennCare enrollee pursuant to a Prescriber's authorization. Reimbursement rates will vary depending on the type of provider (i.e. ambulatory or long term care). Ambulatory pharmacy claims will be reimbursed by paying the lesser of: a) the provider's usual and customary charge to the general public; or b) A.W.P. minus 13% plus a \$2.50 dispensing fee (brandnames); or c) A.W.P. minus 13% plus a \$3.00 dispensing fee (generics); or d) MAC plus a \$3.00 dispensing fee if the days supply is equal to or greater than 28 (brandnames); or b) A.W.P. minus 13% plus a \$6.00 dispensing fee (generics); or c) A.W.P. minus 13% plus a \$2.50 dispensing fee if the days supply is less than 28 (brandnames); or d) A.W.P. minus 13% plus a \$3.00 dispensing fee (generics); or e) MAC plus a \$6.00 dispensing fee if the days supply is equal to or greater than 28; or f) MAC plus a \$3.00 dispensing fee if the days supply is less than 28; or g) the provider's usual and customary charge to the general public. If the pharmacy provider is a PHS (340B) provider then the pharmacy provider must bill TennCare its PHS (340B) acquisition price for TennCare recipients served through the PHS (340B) program (see 59 FR 25112, or Federal Register, Vol. 59, No. 92, Friday, May 13, 1994, page 25112).

**Section 3.2: Obligation for Payment.** Obligation for payment under this Agreement for any Pharmaceutical Services rendered to a TennCare enrollee is solely that of TennCare. In no event shall TennCare be obligated to pay any claim from Pharmacy unless and until sufficient funds have been made available to TennCare.

**Section 3.3: Payment in Full.** Pharmacy shall accept as payment in full for Pharmaceutical Services rendered to TennCare enrollees such amounts as are established by this TennCare Agreement. In no event shall Pharmacy bill a TennCare enrollee for the difference between the Pharmacy's Usual and Customary Charge and the amount TennCare has agreed to reimburse the Pharmacy. Pharmacy may collect from a TennCare enrollee Co-payments, Co-insurance Charges, Deductibles or other charges for services not covered under the TennCare waiver.

Section 3.4: TennCare enrollee Hold Harmless. This section shall apply only to such TennCare enrollees as may be afforded the protection of this Section by applicable statutes or regulations. To the extent this Section conflicts with any other provisions of this Agreement, including, without limitation, Section 3.3, the terms and conditions of this Section shall apply. Pharmacy shall accept as payment in full for Pharmaceutical Services rendered to TennCare enrollees such amounts as are paid by TennCare pursuant to this Agreement. In no event, including, but not limited to, non-payment by TennCare for Pharmaceutical Services rendered to TennCare enrollees by Pharmacy, insolvency of TennCare, or breach by TennCare of any term or condition of this Agreement, shall Pharmacy bill, charge, collect a deposit from, seek compensation, remuneration or reimbursement from, or have any recourse against any TennCare enrollee or persons acting on behalf of the TennCare enrollee for Pharmaceutical Services eligible for reimbursement under this Agreement; provided, however, that Pharmacy may collect from the TennCare enrollee Co-payment, Co-insurance Charges, Deductibles or other charges for services not covered under the TennCare waiver. The provisions of this Section shall (a) apply to all Pharmaceutical Services rendered while this Agreement is in force; (b) with respect to Pharmaceutical Services rendered while this Agreement is in force, survive the termination of this

Agreement regardless of the cause of termination; (c) be construed to be for the benefit of TennCare enrollees; and (d) supersede any oral or written agreement, existing or subsequently entered into, between Pharmacy and a TennCare enrollee or person acting on a TennCare enrollee's behalf, that required TennCare enrollee to pay for Pharmaceutical Services.

**Section 3.5: Prompt Payment:** Pharmacy shall promptly submit any and all information needed to make payment.

**Section 3.6: Time Period for Payment:** Upon receipt of a clean claim (into the POS pharmacy claims processing system) properly submitted by Pharmacy, TennCare shall pay Pharmacy within thirty (30) calendar days.

**Section 3.7:** Acceptance of Surety and TennCare enrollees: Pharmacy shall accept payment or appropriate denial made by TennCare as payment in full for covered services provided and shall not solicit or accept any surety or guarantee of payment from TennCare enrollees. TennCare enrollees shall include the patient, parent(s), guardian, spouse or any other legally responsible person of the patient being served.

**Section 3.8: TennCare Reimbursement:** Pharmacy shall be required to accept TennCare reimbursement amounts for services provided under the Participation Agreement between Pharmacy and TennCare to TennCare enrollees, and shall not be required to accept TennCare reimbursement amounts for services provided to persons who are covered by another health plan.

Section 3.9: Non-covered therapeutic Drugs: Under the TennCare Program, Pharmacy will be reimbursed for covered services if such services are medically necessary and on the TennCare PDL; provided, however, that non-covered therapeutic classes, (e.g., Appetite suppressants, drugs to treat infertility), DESI, LTE and IRS drugs shall be explicitly excluded. For these purposes, (a) "DESI" means Drug Efficacy Study and Implementation whereby drugs may be found to be LTE or IRS, (b) "LTE" means less than effective as determined by the Food and Drug Administration and (c) "IRS" means identical, related or similar to DESI or LTE. A partial listing of these DESI, LTE and IRS drugs may be found on the CMS website: http://www.cms.hhs.gov/medicaid/drugs/desi.pdf.

Covered services under the Agreement shall include Early and Periodic Screening, Diagnosis and Treatment ("EPSDT") services as medically necessary in accordance with 42 CFR Part 441 Subpart B and the Omnibus Budget Reconciliation Act of 1989 for children under the age of 21. Such screening shall be done in accordance with the periodicity schedule set forth in, and all components of this program shall be consistent with, the latest "American Academy of Pediatrics Recommendations for Preventative Pediatric Health Care." Pharmacy shall make all treatment decisions under the Agreement with respect to children under the age of 21 based upon medical necessity in light of such child's individual medical and behavioral health needs.

**Section 3.10: Generic Drugs:** The TennCare pharmacy program described in this agreement uses a maximum allowable cost (MAC) pricing system for multisource generic drugs (as defined in First Databank). MAC prices for generic drugs will be published and available on the First Health website at the following address: https://tennessee.fhsc.com/secure/providers/mac/default.asp.

If the brand name drug has a MAC (maximum allowable cost) price associated with its reimbursement, the pharmacist may either contact the TennCare Pharmacy Program at 1-888-816-1680 for override instructions or enter a DAW code of "1" (or the code designated by TennCare) in the appropriate NCPDP field.

## SECTION 4 RELATIONSHIP BETWEEN PARTIES

**Section 4.1: Relationship between TennCare and Pharmacy.** The relationship between TennCare and Pharmacy is that of independent entities, and nothing in this Agreement or otherwise shall be construed or deemed to create any other relationship, including one of employment, partnership, agency, joint venture or associates of one another.

**Section 4.2: Relationship between Pharmacy and TennCare Enrollees.** The relationship between Pharmacy and TennCare enrollees is that of pharmaceutical provider and patient. Nothing in this agreement shall be construed to require Pharmacy to provide any Pharmaceutical Service if in the Pharmacy's professional judgment such Pharmaceutical Service should not be provided.

**Section 4.3:** Relationship between Pharmacy and Long Term Care Facility. The relationship between the pharmacy and the covered facility is that of an independent Pharmacy. Nothing in this agreement or otherwise shall be considered or deemed to create a relationship between the TennCare and the long-term care facility.

**Section 4.4: Restrictions on Change in Relationship Between TennCare and Pharmacy:** To the extent required by TennCare, Pharmacy shall not enter into any subsequent agreements or subcontracts for any of the work contemplated under the Provider Agreement without approval of TennCare.

#### SECTION 5 LIABILITY INSURANCE AND INDEMNIFICATION

Section 5.1: Pharmacy Liability Insurance. Participating pharmacies shall procure and maintain, at Pharmacy's sole expense, professional liability and malpractice insurance with limits of no less than One Million Dollars (\$1,000.000) for each claim and of no less than Three Million Dollars (\$3,000,000) aggregate, as well as comprehensive general liability insurance. Pharmacy shall also assure that all pharmacists and other health care professionals employed or under contract with Pharmacy to render Pharmaceutical Services to TennCare enrollees procure and maintain such insurance, unless they are covered under Pharmacy's insurance policies. Pharmacy's, pharmacists', and other health care professionals' professional liability insurance shall be either occurrence or claims made with an extended period reporting option under such terms and conditions as may be reasonably required by TennCare . Upon request by TennCare, Pharmacy shall submit to TennCare in writing evidence of insurance coverage. Pharmacy shall notify TennCare in writing, to the attention of the TennCare Pharmacy Director, fifteen (15) days prior to any denial of, restriction on, or termination of Pharmacy's general or professional liability insurance, except where such insurance is immediately replaced by equivalent insurance not subject to such denial, restriction, or termination. Pharmacy shall also notify TennCare, to the attention of the TennCare Pharmacy Director, within fifteen (15) days of any settlement or judgment that the Pharmacy is aware of adverse to Pharmacy which resulted from a malpractice complaint against Pharmacy.

If the Pharmacy is a Tennessee governmental entity, it is governed by the provisions of the Tennessee Government Tort Liability Act, *Tennessee Code Annotated*, Sections 29-20-101 *et seq.*, for causes of action sounding in tort. However, as a condition of entering into this Agreement with the State, the Pharmacy agrees to carry and produce proof thereof, adequate professional malpractice liability insurance on the Pharmacy's professional employees who perform any professional services under this Agreement.

**Section 5.2: Indemnification.** Pharmacy and TennCare each agree to indemnify and hold harmless the other party from any and all claims, liabilities, damages, or judgments imposed upon, incurred by or asserted against the other party which arise solely out of or derive solely from the negligence or fault of the first party.

If the Pharmacy is a Tennessee governmental entity, it is governed by the provisions of the Tennessee Government Tort Liability Act, *Tennessee Code Annotated*, Sections 29-20-101 *et seq.*, for causes of action sounding in tort. Further, no contract provision requiring a Tennessee political entity to indemnify or hold harmless the State beyond the liability imposed by law is enforceable because it appropriates public money and nullifies governmental immunity without the authorization of the General Assembly.

## SECTION 6 LAWS, REGULATIONS, AND LICENSES

**Section 6.1: Laws, Regulations and Licenses.** Participating pharmacies shall maintain all federal, state, and local licenses, certifications, and permits, without restriction, required to provide Pharmaceutical

Services to TennCare enrollees and shall comply fully with all applicable laws and regulations. Pharmacy shall notify TennCare in writing, to the attention of the TennCare Pharmacy Director, within ten (10) days of any suspension, revocation, condition, limitation, qualification, or other restriction of Pharmacy's license by any state in which Pharmacy is authorized to provide Pharmaceutical Services which would prohibit Pharmacy from performing any of its obligations under this Agreement.

Section 6.2: Exclusion from Participation in Government Health Care Programs. Pharmacy shall immediately notify the TennCare Pharmacy Director of the exclusion of any pharmacist employed by the Pharmacy by the Federal Office of Inspector General (OIG), the Department of Health and Human Services (HHS) or CMS. No pharmacists who have been excluded from participation in any government health care programs (Medicare, Medicaid, or other state or federal government health care programs) shall be permitted to participate in the TennCare program unless they can document that Federal OIG, CMS or HHS has fully reinstated them as a participating provider. Pharmacy shall immediately notify TennCare if it has been excluded from participation in the Medicare and/or Medicaid programs pursuant to Sections 11.28 or 11.56 of the Social Security Act or is otherwise not in good standing with the TennCare Program. Failure to so notify TennCare shall constitute a material breach of the Agreement. Failure to provide TennCare with this information may also be cause for termination of the Pharmacy from participation in the TennCare program and recoupment of any and all reimbursements made to Pharmacy during the time period such excluded provider was providing Pharmaceutical Services to TennCare enrollees.

**Section 6.3: Compliance with Legal Regulations:** Both TennCare and Pharmacy agree to recognize and abide by all state and federal laws, regulations and guidelines applicable to the scope of services provided or anticipated to be provided by this Agreement, including the Tennessee state plan, 42 CFR 431.107, 42 CFR 455 subpart B, and Section 1200-13-1-.05(1)(a).

**Section 6.4: Incorporation by Reference of Federal and State Law/Regulation:** By reference, this agreement incorporates all applicable federal and state laws and regulations and any applicable court orders or consent decrees, and any and all revisions of such laws or regulations shall automatically be incorporated into the Participation Agreement as they become effective.

**Section 6.5: Non-Discrimination:** In accordance with the following federal and state statutory law no person on the grounds of race, color, national origin, disability, age, religion or sex shall be excluded from participation in or be denied benefits of, or be otherwise subjected to discrimination in the performance of this Agreement. The Pharmacy, in accordance with the following federal and state statutory laws, shall upon request by TennCare show proof of such non-discrimination:

- a) Title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d) and regulations issued pursuant thereto, 45 C.F.R. Part 80.
- b) Section 504 of the Rehabilitation Act of 1973, as amended, 29 U.S.C. 794, which prohibits discrimination on the basis of handicap in programs and activities receiving or benefiting from federal financial assistance, and regulations issued pursuant thereto, 45 C.F.R. Part 84.
- c) The Age Discrimination Act of 1975, as amended, 42 U.S.C. 6101 et seq., which prohibits discrimination on the basis of age in programs or activities receiving or benefiting from federal financial assistance.
- d) The Omnibus Budget Reconciliation Act of 1981, P.E. 97-35, which prohibits discrimination on the basis of sex and religion in programs and activities receiving or benefiting from federal financial assistance.
- e) Americans with Disabilities Act, 42 U.S.C. Section 12101 et seq., and regulations issued pursuant thereto, 28 C.F.R. Parts 35, 36.
- f) Title IX of the Education Amendments of 1972 regarding education programs and activities.

g) In the event of a TennCare Pharmacy Provider determining that he/she cannot establish and/or maintain a professional relationship with a TennCare enrollee or an enrollee's representative, and will no longer provide pharmacy services for that enrollee, this decision is to be reported directly to the TennCare Pharmacy Program. That determination is to be reported to the TennCare Pharmacy Program within twenty four (24) hours. In the event of the date occurring on a weekend (Saturday or Sunday) or a State/Federal holiday the determination is to be reported on the following business day. The Pharmacy Provider is to report the determination to the TennCare Pharmacy Program at 1-800-342-3145.

**Section 6.5.1.: Complaints of Discrimination:** All complaints of discrimination applicable to the mandatory federal and state statutory law, as listed in Section 6.5., related to the performance of this Agreement will be investigated by TennCare. The resolution of all discrimination complaint will be the responsibility of TennCare.

#### Section 6.6: HIPAA Compliance

**Section 6.6.1:** In accordance with HIPAA regulations, the Pharmacy shall, at a minimum, comply with the following requirements:

- a) As a party to this Agreement, the Pharmacy hereby acknowledges its designation as a covered entity under the HIPAA regulations;
- b) The Pharmacy shall comply with the transactions and code set, privacy, and security regulations, once finalized, of the Health Insurance Portability and Accountability Act of 1996 by their designated compliance dates. Compliance includes meeting all required transaction formats and code sets with the specified data partner situations required under the regulations.
- c) The Pharmacy shall transmit/receive from/to its provider, subcontractors, clearinghouses and TennCare all transactions and code sets required by the HIPAA regulations in the appropriate standard formats as specified under the law and as directed by TennCare so long as TennCare direction does not conflict with the law;
- d) The Pharmacy shall agree that if it is not in compliance with all applicable standards defined within the transactions and code sets, privacy, security and all subsequent HIPAA standards, that it will be in breach of this Agreement and will then take all reasonable steps to cure the breach or end the violation as applicable. Since inability to meet the transactions and code sets requirements, as well as the privacy and security requirements can bring basic business practices between TennCare and the Pharmacy and between the Pharmacy and its providers and/or subcontractors to a halt, if for any reason the Pharmacy cannot meet the requirements of this Section, TennCare may terminate this Agreement in accordance with Section 4-2;
- e) Protected Health Information (PHI) data exchanged between the Pharmacy and TennCare is intended to be used only for the purposes of health care operations, payment and oversight and its related functions. All PHI data not transmitted for the purposes of health care operations and its related functions, or for purposes allowed under the federal HIPAA regulations will be de-identified to protect the individual enrollee's PHI under the privacy act;
- f) Disclosures of Protected Health Information from the Pharmacy to TennCare shall be restricted as specified in the HIPAA regulations and will be permitted for the purposes of: health care operation, payment and oversight, obtaining premium bids for providing health coverage, modifying, amending or terminating the group health plan. Disclosures to TennCare from the Pharmacy shall be as permitted and/or required under the law.

- g) The Pharmacy shall report to TennCare within five (5) days of becoming aware of any use or disclosure of Protected Health Information in violation of this Agreement by the Pharmacy, its officers, directors, employees, subcontractors or agents or by a third party to which the Pharmacy disclosed Protected Health Information;
- h) The Pharmacy shall specify in its agreements with any agent or subcontractor of the Pharmacy that will have access to Protected Health Information that such agent or subcontractor agrees to be bound by the same restrictions, terms and conditions that apply to the Pharmacy pursuant to this Section;
- i) The Pharmacy shall make available to TennCare enrollees the right to amend their Protected Health Information data in accordance with the federal HIPAA regulations. The Pharmacy shall also send information to enrollees educating them of their rights and necessary steps in this regard;
- j) The Pharmacy shall make an enrollee's PHI data accessible to TennCare immediately upon request by TennCare;
- k) The Pharmacy shall make available to TennCare within ten (10) days of notice by TennCare to the Pharmacy such information as in the Pharmacy's possession and is required for TennCare to make the accounting of disclosures required by 45 CFR § 164.528. At a minimum, the Pharmacy shall provide TennCare with the following information:
  - 1) the date of disclosure,
  - the name of the entity or person who received the HIPAA protected information, and if known, the address of such entity or person.
  - 3) a brief description of the Protected Health Information disclosed, and
  - 4) a brief statement of the purpose of such disclosure which includes an explanation of the basis for such disclosure.

In the event that the request for an accounting of disclosures is submitted directly to the Pharmacy, the Pharmacy shall within two (2) days forward such request to TennCare. It shall be TennCare's responsibility to prepare and deliver any such accounting requested. Additionally, the Pharmacy shall institute an appropriate record keeping process and procedures and policies to enable the Pharmacy to comply with the requirements of this Section;

- The Pharmacy shall make its internal policies and procedures, records and other documentation related to the use and disclosure of Protected Health Information available to the Secretary of Health and Human Services for the purposes of determining compliance with the HIPAA regulations upon request;
- m) The Pharmacy shall create and adopt policies and procedures to periodically audit adherence to all HIPAA regulations, and for which Pharmacy acknowledges and promises to perform, including but not limited to, the following obligations and actions:
  - 1) Safeguards. Pharmacy agrees to use administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of the EPHI Pharmacy creates, receives, maintains, or transmits on behalf of TennCare.
  - 2) Pharmacy's Agents. Pharmacy agrees to ensure that any agent, including a subcontractor, to whom it provides EPHI that was created, received, maintained,

- or transmitted on behalf of TennCare agrees to use reasonable and appropriate safeguards to protect the EPHI.
- 3) Notification of Security Incident. Pharmacy agrees to report to TennCare any use or disclosure of TennCare enrollee PHI or of any security incident of which Pharmacy becomes aware.
- n) Upon termination, cancellation, expiration or other conclusion of the Agreement, and in accordance with Sections 2-11 and 2-13 of this Agreement, the Pharmacy will, if feasible, return or destroy all PHI, in whatever form or medium (including any electronic medium) and all copies of an any data or compilations derived from and allowing identification of any individual who is a subject of that PHI. The Pharmacy will complete such return or destruction as promptly as possible, but not later than 30 days after the effective date of the termination, cancellation, expiration or other conclusion of the Agreement. The Pharmacy will identify any PHI that cannot feasibly be returned to or destroyed. Within such 30 days after the effective date of the termination, cancellation, expiration or other conclusion of the Agreement, the Pharmacy will: (1) certify on oath in writing that such return or destruction has been completed; (2) identify any PHI which can not feasibly be returned or destroyed; and (3) certify that it will only use or disclose such PHI for those purposes that make its return or destruction infeasible;
- o) The Pharmacy shall implement all appropriate administrative, technical and physical safeguards to prevent the use or disclosure of PHI other than pursuant to the terms and conditions of this Agreement, including but not limited to, confidentiality requirements in 45 CFR parts 160 and 164:
- p) The Pharmacy shall set up appropriate mechanisms to ensure minimum necessary access of their staff to Protected Health Information:
- q) The Pharmacy shall create and implement policies and procedures to address present and future HIPAA regulation requirements as needed to include: use and disclosure of data; de-identification of data; minimum necessity access; accounting of disclosures; patients rights to amend, access, request restrictions, and right to file a complaint;
- r) The Pharmacy shall provide an appropriate level of training to its staff and enrollees regarding HIPAA related policies, procedures, enrollee rights and penalties prior to the HIPAA implementation deadlines and at appropriate intervals thereafter;
- s) The Pharmacy shall be allowed to use and receive information from TennCare where necessary for the management and administration of this Agreement and to carry out business operations;
- t) The Pharmacy shall be permitted to use and disclose PHI for the Pharmacy's own legal responsibilities;
- u) The Pharmacy will adopt the appropriate procedures and access safeguards to restrict and regulate access to and use by Pharmacy employees and other persons performing work for said Pharmacy to have only minimum necessary access to personally identifiable data within their organization;
- v) The Pharmacy will continue to protect personally identifiable information relating to individuals who are deceased;
- w) The Pharmacy will be responsible for informing its enrollees of their privacy rights in the manner specified under the regulations;

- x) The Pharmacy must make available protected health information in accordance with 45 CFR § 164.524:
- y) The Pharmacy must make available protected health information for amendment and incorporate any amendments to protected health information in accordance with 45 CFR §164.526; and
- z) The Pharmacy shall obtain a third (3<sup>rd</sup>) party certification of their HIPAA transaction compliance before July 1, 2003.

**Section 6.2:** In accordance with HIPAA regulations, TennCare shall, at a minimum, adhere to the following guidelines:

- TennCare shall make its individually identifiable health information available to enrollees for amendment and access as specified and restricted under the federal HIPAA regulations;
- TennCare shall set up policies and procedures for minimum necessary access to individually identifiable health information with its staff regarding plan administration and oversight;
- c) TennCare shall adopt a mechanism for resolving any issues of non-compliance as required by law; and
  - TennCare shall establish similar HIPAA data partner agreements with its subcontractors and other business associates.

#### SECTION 7 SYMBOLS AND TRADEMARKS

**Section 7.1: Use By Pharmacy.** Participating pharmacies shall have the right to designate and make oral or published reference to Pharmacy as a Participating Pharmacy; provided, however, that Pharmacy shall not otherwise use TennCare's name or its trademark for any advertising unless first approved in writing in advance by TennCare.

**Section 7.2: Use By TennCare.** TennCare shall have the right to designate and make oral or published reference to Pharmacy as a Participating Pharmacy; provided, however, that TennCare shall not otherwise use Pharmacy's name or its trademark for any advertising unless first approved in advance by Pharmacy.

#### SECTION 8 BOOKS AND RECORDS

Section 8.1: Access To and Release of Books and Records. Subject to applicable confidentiality laws and regulations, during regular business hours and with or without notice and demand, TennCare shall have access to all information and records or copies of records maintained by Pharmacy related to Pharmaceutical Services provided by Pharmacy under this Agreement or related to analysis of the efficiency of healthcare management techniques by TennCare. Unless otherwise required by applicable laws or regulations, TennCare shall have such access at any time up to five (5) years following the date the Pharmaceutical Service was provided. Pharmacy shall provide records or copies of records requested by TennCare or their duly authorized agents within thirty (30) days from the date such request is made, or within shorter time [not less than fourteen (14) days] as may be required by applicable laws or regulations. Pursuant to Section 9, in the event of termination, Pharmacy shall immediately make available, to TennCare, or its designated representative, any or all records, whether medical, pharmacy, or financial, related to the provider's activities undertaken pursuant to the Agreement. The provision of such records shall be at no expense to TennCare.

- **Section 8.2: Compliance With Laws and Regulations.** The federal, state, and local governments and any of their authorized representatives shall have access to, and TennCare and Pharmacy are authorized to release, in accordance with applicable laws and regulations, all information and records, or copies of such, within the possession of TennCare or Pharmacy, which are pertinent to and involve transactions related to this Agreement and access to which is necessary to comply with laws and regulations applicable to TennCare.
- **Section 8.3: Privacy of TennCare Enrollee's Records.** TennCare and Pharmacy shall maintain the confidentiality of all information regarding TennCare enrollees in accordance with any applicable state and federal laws and regulations, including the standards and requirements of HIPAA.
- **Section 8.4: Confidential Business Information.** TennCare and Pharmacy shall take all necessary steps to provide maximum protection to the other party's trade secrets and other confidential business information, to the extent possible under state and federal law.
- **Section 8.5: Confidentiality of Utilization Review Information.** Any records, data or other information imparted to Pharmacy or any of its employees in connection with utilization review panels established by TennCare shall be maintained as strictly confidential. Such information shall be used solely in the exercise of the proper functions of said panel(s). Pharmacy and its employees shall not disclose said information to any person, firm or entity, and shall notify TennCare immediately of any demand or request for any such information from any third party.
- **Section 8.6: Maintenance of Medical Records-Access:** Pharmacy shall maintain an adequate record system for recording services, servicing Pharmacy, charges, dates and all other commonly accepted information elements for services rendered to TennCare enrollees pursuant to the participation agreement (including but not limited to such records as are necessary for the evaluation of the quality, appropriateness, and timeliness of services performed under Pharmacy Agreement). This includes the maintenance of a signature log which will list the recipient's name, date the prescription(s) is/are picked up, and the prescription number(s). TennCare enrollees and their representatives shall be given access to their medical/pharmacy records, to the extent and in the manner provided by Tennessee Code Annotated §§63-2-101 and 63-2-102, and, be given copies thereof upon request.
- **Section 8.7: Maintenance of Medical Records Duration:** Pharmacy shall maintain any and all records for a period not less than five (5) years from the termination of the Participation Agreement and shall retain the records further if they are under review or audit until the review or audit is complete. Said records shall be made available for fiscal audit, medical audit, medical review, utilization review, and other periodic monitoring upon request of an authorized representative of TennCare.
- **Section 8.8: Right to Inspection by Government Entities:** TennCare, the U.S. Department of Health and Human Services, and the Office of Inspector General Comptroller shall have the right to evaluate through inspection, whether announced or unannounced, or other means any records pertinent to the Participation Agreement including quality, appropriateness, and timeliness of services, and such evaluation, if performed, shall be performed with the cooperation of Pharmacy. Upon request, Pharmacy shall assist in such reviews including the provision of complete copies of pharmacy records.
- **Section 8.9: Report Submission:** Pharmacy will submit all reports and clinical information required by TennCare.
- **Section 8.10: Safeguarding Information:** Strict standards of confidentiality of records including, but not limited to, patient medical/pharmacy records and other similar records shall be maintained in accordance with all applicable state and federal laws and regulations.
- **Section 8.11: Monitoring of Services Rendered:** Whether announced or unannounced, TennCare may monitor the services rendered to TennCare enrollees.

**Section 8.12: External Review:** Whether announced or unannounced, Pharmacy shall participate and cooperate in any internal and external quality review, audit, utilization review, peer review, TennCare Pharmacy Advisory Committee, TennCare DUR board, and appeal procedures established by TennCare.

#### SECTION 9 TERM AND TERMINATION

**Section 9.1: Term.** Unless earlier terminated in the manner provided below, this Agreement shall be in effect commencing on the date first above written of the current year and shall continue thereafter for successive periods of twelve (12) months until terminated by either party upon written notice to the other party not less than sixty (60) days prior to the initial or any subsequent expiration date.

**Section 9.2: Termination by Pharmacy.** This Agreement may be terminated at any time by Pharmacy upon sixty (60) days written notice to TennCare.

**Section 9.3: Termination by TennCare.** This agreement may be terminated at any time by TennCare upon written notice to Pharmacy:

- a) following written notice from TennCare that Pharmacy is in material breach of its obligations under this Agreement or any applicable agreement and the expiration, without cure of such material breach, of thirty (30) days after Pharmacy's receipt of such notice; or
- b) in the event Pharmacy willfully refuses to provide Pharmaceutical Services to a TennCare enrollee, except as provided in Section 4.2; or
- c) in the event Pharmacy's loss or suspension of licensure of loss of liability insurance required under this Agreement; or
- d) following TennCare's receipt from Pharmacy of an objection to a proposed amendment to this Agreement pursuant to Section 10.1(b); or
- e) the Pharmacy has been excluded from participation in the TennCare program by TennCare, a TennCare MCO, CMS, Federal OIG or HHS: or
- f) the Pharmacy has knowingly allowed a pharmacist who has been excluded from participation in the TennCare program by TennCare, a TennCare MCO, CMS, Federal OIG or HHS to provide pharmaceutical services to TennCare enrollees; or
- g) the Pharmacy has not complied with all of the emergency supply provisions contained in Section 2.9. above and any subsequent agreement amendments or revisions to court orders or consent decrees that pertain to the supply of emergency supply dispensings; or
- h) the Pharmacy refuses to provide pharmacy services to a TennCare member solely because the member is unable to pay any or all pharmacy co-payments; or
- i) failure to maintain medical records and access as specified in Section 8.6; or
- j) failure to display notice of appeal as specified in Section 10.8.

**Section 9.4: Continuation Provisions.** Pharmacy shall continue as a Participating Pharmacy under this Agreement during the notice period specified in Sections 9.2 and 9.3 unless otherwise notified by TennCare in writing of the suspension of all or part of its rights and obligations as a Participating Pharmacy. Upon termination of this Agreement, Pharmacy shall continue to perform the obligations of Participating Pharmacy under the Agreement in effect between TennCare and the Pharmacy at the time of termination which provide for continuation of such obligations, including those relating to continued provision of Pharmaceutical Services to TennCare enrollees, at the rates and for the period specified in such agreement, unless otherwise agreed by

TennCare.

**Section 9.5: Application of Pharmacy**. It is the understanding of the parties that this Agreement shall be executed first by Pharmacy and upon such execution shall be an application by Pharmacy to become a party to this Agreement. As part of such application, Pharmacy shall complete the information in Exhibit A (Pharmacy Application). This signing of this Agreement by Pharmacy shall constitute an offer only, unless and until it is approved by TennCare in the State of Tennessee. This application by Pharmacy shall be accepted by TennCare only if Pharmacy meets all participation criteria established by TennCare and only at TennCare's sole discretion.

#### SECTION 10 MISCELLANEOUS

**Section 10.1: Amendment.** This Agreement may be amended by TennCare. TennCare may amend this Agreement (a) to comply with applicable court orders, consent decrees, laws or regulations or (b) to affect any necessary policy changes by giving thirty (30) days written notice of an amendment to Pharmacy.

**Section 10.2: Assignment.** TennCare may assign all or any of its rights or responsibilities under this Agreement to any entity controlling, controlled by, or under common control with TennCare. Pharmacy acknowledges that persons and entities under contract with TennCare may perform certain administrative services under this Agreement. Pharmacy may not assign any of its rights or responsibilities under this Agreement to any person or entity without the prior written consent of TennCare, which consent shall not be unreasonably withheld.

**Section 10.3: Entire Agreement.** This Agreement, the Pharmacy Application and the Pharmacy Manual constitute the entire Agreement between the parties with respect to its subject matter.

**Section 10.4: Notices.** Any notice or other communication required or permitted under this Agreement shall be in writing. The notice or communication shall be deemed to have been given when delivered in person; or if delivered by United States mail, on the date mailed, proper postage prepaid and properly addressed to the address set forth next to the appropriate party's name at the end of this Agreement or to another more recent address of which the sending party has received written notice. Notices may also be sent via facsimile and through a web-based bulletin board process and e-mail and posted on TennCare's website.

Section 10.5: Governing Law. This Agreement shall be construed in accordance with all applicable laws of the State of Tennessee.

Section 10.6: Indemnification – State of Tennessee: Pharmacy agrees to indemnify and hold harmless the State of Tennessee as well as its officers, agents, and employees from and against any and all claims, liabilities, losses, and causes of action which may arise, accrue, or result to any person, firm, corporation or other entity which may be injured or damaged as a result of acts, omissions, bad faith, negligence, or willful misconduct on the part of the Pharmacy, its employees, or any other person acting for or on its or their behalf relating to this contract. Pharmacy further agrees that it shall be liable for the reasonable costs of attorneys for the State in the event such service is necessitated to enforce the terms of this contract or otherwise enforce the obligations of Pharmacy to the State. In the event of any such suit or claim, Pharmacy shall give the State immediate notice thereof and shall provide all assistance required by the State in the State's defense. The State shall give Pharmacy written notice of any such claim or suit and Pharmacy shall have the full right and obligation to conduct Pharmacy's own defense thereof. Nothing contained herein shall be deemed to accord to Pharmacy, through its attorney(s), the right to represent the State of Tennessee in any legal matter, such rights being governed by Tenn. Code. Ann. § 8-6-106.

However, if the Pharmacy is a Tennessee governmental entity, it is governed by the provisions of the Tennessee Government Tort Liability Act, *Tennessee Code Annotated*, Sections 29-20-101 *et seq.*, for causes of action sounding in tort. Further, no contract provision requiring a Tennessee political entity to indemnify or hold harmless the State beyond the liability imposed by law is enforceable because it appropriates public money and nullifies governmental immunity without the authorization of the General

Assembly. In the event of any lawsuit or claim arising out of this Agreement, if the Pharmacy is a governmental entity, the Pharmacy shall give the State immediate notice thereof and shall provide all assistance required by the State in the State's defense. In addition, in the situation where the Pharmacy is a governmental entity, the State shall give Pharmacy written notice of any such claim or suit and Pharmacy shall have the full right and obligation to conduct Pharmacy's own defense thereof. Nothing contained herein shall be deemed to accord to Pharmacy, through its attorney(s), the right to represent the State of Tennessee in any legal matter, such rights being governed by <u>Tenn. Code. Ann.</u> § 8-6-106.

**Section 10.7: Compliance with Appeals Process:** Pharmacy agrees to comply with the appeal process including but not limited to assisting a TennCare enrollee by providing appeal rights, appeal forms and contact information including the appropriate address for submitting appeals for state level review.

**Section 10.8: Displaying Notice of Appeal:** Pharmacy agrees to display notices of TennCare enrollee's right to appeal adverse decisions affecting services and other applicable notices in public areas of their facility(ies) in accordance with TennCare rules, including TennCare Rules 1200-13-13-.11 and 1200-13-14-.12.

**Section 10.9: Conflict of Interest:** The Pharmacy warrants that no part of the total Agreement amount provided herein shall be paid directly or indirectly to any officer or employee of the State of Tennessee as wages, compensation, or gifts in exchange for acting as officer, agent, employee, subcontractor, or consultant to the Pharmacy in connection with any work contemplated or performed relative to this Agreement unless otherwise authorized by the Commissioner, Tennessee Department of Finance and Administration.

This Agreement may be terminated by TENNCARE if it is determined that the Pharmacy, its agents or employees offered or gave gratuities of any kind to any officials or employees of the State of Tennessee. The CONTRACTOR certifies that no member of or delegate of Congress, the General Accounting Office, DHHS, HCFA or any other federal agency has or will benefit financially or materially from this Agreement.

**Section 10.10: Offer of Gratuities.** By signing this Agreement, the Pharmacy signifies that no member of or a delegate of Congress, nor any elected or appointed official or employee of the State of Tennessee, the General Accounting Office, Department of Health and Human Services, HCFA, or any other federal agency has or will benefit financially or materially from this procurement unless otherwise authorized by the Commissioner, Tennessee Department of Finance and Administration. This Agreement may be terminated by TENNCARE if it is determined that gratuities of any kind were offered to or received by any of the aforementioned officials or employees from the Pharmacy, its agent, or employees.

**Section 10.11:** Lobbying. The Contractor further certifies by signing this Agreement, to the best of its knowledge and belief, that Federal funds have not been used for lobbying in accordance with 45 CFR 93, Appendix A

Section 10.12: Fraud Investigations: Pharmacy shall immediately report to the TennCare Pharmacy Director or the Tennessee Bureau of Investigation Medicaid Fraud Control Unit ("TBI MFCU") any suspicion or knowledge of fraud and/or abuse, including but not limited to the false or fraudulent filings of claims and/or the acceptance or failure to return monies allowed or paid on claims known to be false, incorrect, inaccurate or fraudulent. The reporting entity shall not attempt to investigate or resolve the reported suspicion, knowledge or action without informing the TennCare Pharmacy Director or the TBI MFCU and must cooperate fully in any investigation by the TennCare Pharmacy Director or the TBI MFCU or subsequent legal action that may result from such an investigation. Pharmacy, shall, upon request, make available to the TennCare Pharmacy Director or the TBI MFCU any and all administrative, financial and medical records relating to the delivery of items or services for which TennCare monies are expended. Additionally, the TennCare Pharmacy Director or the TBI MFCU shall be allowed access to place of business and to all records of the Pharmacy, during normal business hours, except under special circumstances when after-hour admission shall be allowed. Special circumstances shall be determined by the TennCare Pharmacy Director or the TBI MFCU.

**Section 10.13: Debarment and Suspension:** To the best of its knowledge and belief, the Pharmacy certifies by its signature to this Agreement that the Pharmacy and its principals:

- a) are not presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from covered transactions by any federal or State department or Pharmacy;
- b) have not within a three (3) year period preceding this Agreement been convicted of, or had a civil judgment rendered against them from commission of fraud, or a criminal offence in connection with obtaining, attempting to obtain, or performing a public (federal, State, or Local) transaction or grant under a public transaction; violation of federal or State antitrust statutes or commission of embezzlement, theft, forgery, bribery, falsification, or destruction of records, making false statements, or receiving stolen property; and
- c) are not presently indicted for or otherwise criminally or civilly charged by a government entity (federal, State, or Local) with commission of any of the offenses detailed in section b. of this certification; and (d) have not within a three (3) year period preceding this Agreement had one or more public transactions (federal, State, or Local) terminated for cause or default.

The Pharmacy's signature on the Agreement shall serve as certification of compliance with this policy. If any doubt exists, officials may check a list maintained by the General Services Administration which lists persons who have been debarred, suspended or proposed for debarment under 45 CRF Part 76 or 48 CFR Part 9, Subpart 9.4. The list can be found at: http://epls.arnet.gov/

If a person is debarred, suspended or proposed for debarment during the term of the Agreement or if the State determines that an agency has misrepresented its status, a decision as to the type of termination action, if any, will be made after a thorough review to ensure the propriety of the proposed action. In this event, the Agreement will not be renewed or extended (other than no-cost time extensions).

Pharmacy has read the TennCare Pharmacy Agreement, completed the Pharmacy Application, executed and delivered this offer the date written below:

Pharmacy Name:	
NCPDP#:	
Pharmacy Type: (Hospital / Long Term Care / Retail / Specialty):	
Signature:	
Printed name:	
Phone number:	
Date:	
Deturn this fully completed signature page and all required application	forms to:

Return this fully completed signature page and all required application forms to:

TennCare Pharmacy Program

310 Great Circle Road

Nashville, Tennessee 37228

or fax it to TennCare toll-free: 888.298.4130